UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF NEW YORK

STEPHEN DUNN AND RAQUEL DIAZ on behalf of all others similarly situated, Plaintiffs, v. ANCIENT BRANDS, LLC, Defendant.	Case No: 5:21-cv-390 (LEK/ML) Judge Lawrence E. Kahn

NOTICE OF MOTION AND MOTION FOR JUDGMENT ON THE PLEADINGS; MEMORANDUM OF POINTS AND AUTHORITIES

TO THE CLERK OF THE COURT AND ALL PARTIES OF RECORD:

PLEASE TAKE NOTICE that Defendant Ancient Brands, LLC ("Ancient Nutrition") will, and hereby does, move the Court, the Honorable J. Kahn presiding, in the United States District Court for the Northern District of New York at the James T. Foley U.S. Courthouse, 445 Broadway, Room 424 Albany, NY 12207-2926 for entry of an order dismissing all causes of action in the First Amended Class Action Complaint filed in this action pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(c). Any amendment would be futile because Plaintiff cannot state any cognizable claim as a matter of law, and this action is properly dismissed without leave to amend.

There is good cause to grant this Motion, including because:

1. Plaintiffs' clams regarding protein-related statements on the front of the product labels are expressly preempted;
2. Plaintiffs' claims regarding the omission of a %DV for protein is impliedly preempted;

3. Plaintiffs fail to plead reliance, causation, or injury resulting from the omission of %DV; and
4. Plaintiffs lack standing to pursue claims predicated on the omission of %DV.

This motion is based on this Notice of Motion and Motion, the Memorandum of Law, Request for Judicial Notice and Declaration of David Kwasniewski and all exhibits thereto filed concurrently herewith, any matters of which this Court may take judicial notice, the files and records in this action and on such other written and oral argument as may be presented to the Court.

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Defendant Ancient Brands, LLC ("Ancient Nutrition") respectfully submits this memorandum of law in support of its Motion for Judgment on the Pleadings.

INTRODUCTION

Ancient Nutrition sells wholesome collagen-based protein supplements, an ingredient with proven benefits for skin, hair, and joints. Its products accurately disclose their protein content, as well as exactly what types of protein are included, in accordance with federal law. For these reasons, the Court correctly concluded in its September 15, 2023, Dismissal Order that Plaintiffs' claims are either expressly or impliedly preempted ("Dismissal Order"). (Dkt. 102.)

Instead of trying to comply with the Court's Dismissal Order, Plaintiffs' Second Amended Complaint ("SAC") adds no additional facts. The only additional allegations are seven paragraphs of attorney argument that have nothing to do with the purchasing decisions of the actual Plaintiffs. (Decl. of David Kwasniewski ("Kwasniewski Decl.") Ex. A (Redline of SAC).) Thus, for the same reasons the Court already found, it fails to plausibly allege Plaintiffs' claims fit within the "narrow gap" between implied and express preemption.

First, for the same reasons set forth in the Court's Dismissal Order at 12-13, Plaintiff's "front-of-label" claims, that Ancient Nutrition misled them with the phrase "20g Protein," are expressly preempted. As the Court already held, Ancient Nutrition's protein content claim was calculated based on the FDA-approved nitrogen method, *id*. at 13, and the SAC adds no new allegations to suggest a claim based on this FDA-approved methodology would be misleading, much less not preempted.

Second, Plaintiffs' claims about %DV are impliedly preempted. As the Court held in its Dismissal Order at page 15, these claims are impliedly preempted because they are "inextricably intertwined" with Plaintiffs' allegations that Ancient Nutrition's labels violate federal law. (Dismissal Order at 15.) The additional allegations of the SAC do not change this fact. The SAC

argues that "consumers" (but not the Plaintiffs, who testified they did not care about %DV) could be misled by Ancient Nutrition's labels because the omission of %DV would lead them to believe the protein was of a higher "quality" than what the products actually contain. (SAC ¶¶ 45-51.) Setting aside that the labels explicitly, and repeatedly, disclose that the products contain collagen, Plaintiffs' new theory is premised on the notion that "consumers" understand the complex web of federal regulations around protein content claims, and based on this understanding, draw inferences about the "quality" of protein in products based on the presence or absence of a %DV claim. If anything, Plaintiffs' new theory is even more "inextricably intertwined" with an alleged violation of federal law than their old theory, and thus impliedly preempted.

Additionally, if Plaintiffs' new theory is not preempted, it should be dismissed because Plaintiffs fail to plausibly allege reliance, causation, or injury, which are essential elements of their claims. The SAC does not claim that Plaintiffs, themselves, bought the collagen powder based on their lawyers' new theory. It does not allege that Plaintiffs believed the omission of %DV meant Ancient Nutrition's products had supposedly higher quality of protein than they actually did. Nor does the SAC allege this omission caused Plaintiffs any actual injury.

Finally, Plaintiffs lack standing under Article III to proceed under their lawyers' new theory. At their depositions, Plaintiffs admitted they were recruited to file this case. They testified that they had little understanding of, and were not motivated by, the absence of a %DV when making their purchases. (Kwasniewski Decl. Ex. B at 52:15-18; 53:20-54:4.) Plaintiffs cannot now assert they really bought the product because they formed opinions about protein quality based on their understanding of federal protein content regulations.

The Court has given Plaintiffs every opportunity to state a claim. They cannot do so. For the reasons above and below, the SAC should be dismissed with prejudice.

FACTS

A. Ancient Nutrition's Bone Broth Protein Product Label

Ancient Nutrition provides consumers with time-tested nutritional products in a modern, convenient form. (SAC ¶ 15.) One of its product lines is "Bone Broth Protein," a series of powdered bone broth products that can be added to hot or cold drinks. (*Id.* ¶ 18.) A statement on the front of each of these products indicates that it provides 20 grams of protein per serving. (*Id.* ¶ 31.) The "Supplement Facts" section of the label includes the protein content per serving by weight but does not provide a %DV.

(Request for Judicial Notice ("RJN") Ex. 3.)

B. Protein Labeling Requirements

The United States Food and Drug Administration ("FDA") extensively regulates the labeling of food products under the Food, Drug, and Cosmetics Act ("FDCA"), including their protein content. 21 C.F.R. § 101.1 *et seq.*

The section of the regulations governing protein information, 21 C.F.R. § 101.9(c)(7), refers to two different protein measurement methodologies. One method calculates protein content by multiplying the nitrogen content of the food in question by a designated constant

("nitrogen method"). 21 C.F.R. § 101.9(c)(7) ("Protein content may be calculated on the basis of the factor 6.25 times the nitrogen content of the food as determined by the appropriate method of analysis as given in the 'Official Methods of Analysis of the AOAC International,' except when official AOAC procedures described in this paragraph (c)(7) require a specific factor other than 6.25, that specific factor shall be used."). The other methodology seeks to quantify protein quality, scaling the amount of protein by a factor ranging from zero to 1 depending on the food's amino acid profile ("PDCAAS"). 21 C.F.R. § 101.9(c)(7)(ii) (calculating "corrected amount of protein" to be "the actual amount of protein (gram) per serving multiplied by the amino acid score corrected for protein digestibility.").[1]

The regulation indicates how each measurement methodology should be used for product labeling. Manufacturers must state the protein content by weight of their products at least once in a nutrition facts panel on their labels, 21 C.F.R. §§ 101.9(c)(7) & (d)(1), and the nitrogen method ***must*** be used to determine that figure. 21 C.F.R. § 101.9(c)(7). Although the regulation refers to

[1] The FDA food labeling regulations adopt a thirty-year-old recommendation by the Food and Agriculture Organization of the UN ("FAO") and the World Health Organization ("WHO") to use PDCAAS to measure protein quality. 21 C.F.R. § 101.9(l)(2)(i) (incorporating by reference a 1991 FAO/WHO report). Since then, the FAO has recognized that PDCAAS no longer reflects the scientific community's best understanding of human nutrition. Dietary Protein Quality Evaluation in Human Nutrition: Report of an FAO Expert Consultation, Food and Agriculture Organization of the United Nations (2013) ("2013 FAO Report") (recommending transition away from PDCAAS), available at https://www.fao.org/ag/humannutrition/35978-02317b979a686a57aa4593304ffc17f06.pdf. Among other issues, it has become apparent that PDCAAS does not accurately capture the actual digestibility of foods, as one of the primary reasons the FAO identified for transitioning away from PDCAAS was the need to focus on digestibility at the "individual amino acid" level. *Id*. at 3 ("dietary amino acids should be treated as individual nutrients and wherever possible data for digestible or bioavailable amino acids should be given in food tables on an individual amino acid basis"). Specifically with regard to the body's ability to use collagen, research suggests that the collagen peptides in supplements are "made of the same amino acids as collagen but are more easily absorbed by our bodies" and that ingesting supplemental collagen produces a range of positive health effects, including improving bone density and skin and joint elasticity. *Are There Benefits to Collagen Supplements?*, THE NEW YORK TIMES, May 13, 2021, https://www.nytimes.com/2019/11/09/style/self-care/collagen-benefits.html.

using PDCAAs to calculate a "corrected amount of protein," the regulation ***never*** indicates that the "corrected amount of protein" should be displayed on a label—instead, the regulation states that it is to be used to calculate a %DV for protein if a label contains such a statement. 21 C.F.R. § 101.9(c)(7)(i)-(iii). The regulation also expressly permits manufacturers to repeat any statements made in the facts panel elsewhere on the label. 21 C.F.R. § 101.13(c).

At the beginning of 2022, the FDA issued guidance to the food industry clarifying various aspects of its labeling requirements and specifically reiterating that statements about protein made outside the facts panel could be based on "either of the methods mentioned" in 21 C.F.R. § 101.9(c)(7). The guidance took the form of a Q&A responding to various questions, including one specifically directed to protein claims:

> **There are separate methods for determining the number of grams of protein in a serving for declaration on the Nutrition Facts label and for determining the percent Daily Value of protein for the Nutrition Facts label (21 CFR 101.9(c)(7)). Which method should be used when calculating protein values for use in protein nutrient content claims?**
>
> The regulation for nutrient content claims in 21 CFR 101.13(o) states that, except as provided in 21 CFR 101.10, compliance with requirements for nutrient content claims in this section and in the regulation in subpart D of this part, will be determined using the analytical methodology prescribed for determining compliance with nutrition labeling in 21 CFR 101.9.
>
> By design, 21 CFR 101.9(c)(7) specifically provides for two different methods for determining protein values. The regulation states, in 21 CFR 101.9(c)(7), that protein content may be calculated on the basis of the factor 6.25 times the nitrogen content of the food as determined by the appropriate method of analysis as given in the "Official Methods of Analysis of the AOAC International," except that when official AOAC procedures described in 21 CFR 101.9(c)(7) require a specific factor other than 6.25, that specific factor shall be used. Additionally, 21 CFR 101.9(c)(7)(ii) provides the method for determining protein content using the protein digestibility-corrected amino acid score for use in calculating the percent Daily Value.
>
> Determination of compliance for protein nutrient content claims will be based on the use of the methods provided in 21 CFR 101.9(c)(7), including either of the methods mentioned above.

(RJN Ex. 9) (highlighting added).

C. Plaintiffs' Testimony

1. Stephen Dunn

Plaintiff Stephen Dunn was deposed on May 2, 2022. He testified that he was recruited as a plaintiff via a Facebook notification indicating that he might be entitled to participate based on his recent purchase. Kwasniewski Decl., Ex. B (Transcript of Deposition of Stephen Dunn (hereinafter "Dunn Dep. Tr.") at 59:17-60:20.) Plaintiff Dunn has only purchased Bone Broth Protein once, when he purchased the vanilla and chocolate versions at a store early in 2020. (Dunn Depo. at 13:7-19.) He testified that he bought the products because the label on the front indicated that they had 20 grams of protein, the products appeared to be easy to add to his diet, and came in flavors that he found appealing. (Dunn Depo. at 25:11-26:5.)

Plaintiff Dunn testified that he did not know what %DV meant, and that it did not matter to him whether there was a %DV for protein on the label, saying "[t]he percentage does not make a difference to me. It was the amount, it was the 20 grams that mattered to me." (Dunn Dep. Tr. at 47:7-10; 49:3-5; 50:10-51:7; 52:15-18; 53:20-54:4).

2. Raquel Diaz

Plaintiff Diaz was deposed on May 3, 2022. She became involved in this proceeding because a friend told her about the opportunity to become a plaintiff in the suit. Kwasniewski Decl., Ex. C (Transcript of Deposition of Raquel Diaz (hereinafter ("Diaz Dep. Tr.") at 14:11-22.)

Before purchasing Bone Broth Protein, Plaintiff Diaz had taken collagen for years because her mother had taken it and she felt that it helped with her hair and nails. (Diaz Dep. Tr. at 11:19-12:4.) Plaintiff Diaz testified that she would have purchased the product for its collagen content alone, even without the protein. (Diaz Dep. Tr. at 57:18-58:6.) Plaintiff Diaz testified that she paid little or no information to other nutrition information on the label, at most "glimpsing" at it. (Diaz Dep. Tr. at 30:16-21.)

D. The Court's Dismissal Order

Plaintiff Diaz and another plaintiff, Diedre Bush, originally initiated this lawsuit on April 5, 2021. (Dkt. 1.) On April 5, 2022, Plaintiffs Diaz and Dunn filed a First Amended Complaint ("FAC") omitting Plaintiff Bush, whose claims were subsequently dismissed. (Dkts. 59, 95.)

The FAC essentially asserted two claims. First, Plaintiffs claimed that the phrase "20g Protein' on the "front" of the label was misleading because Ancient Nutrition did not use the PDCAAS calculation to arrive at that nutrient content claim. Second, Plaintiffs claimed that the label was misleading because it did not include a %DV for protein in the NFP on the "back" of the product.

On September 2, 2022, Ancient Nutrition moved for judgment on the pleadings seeking dismissal of all claims in the FAC. (Dkt. 85.) On September 15, 2022, the Court granted the motion in part. The Court first found that Plaintiffs had standing because they testified they viewed the product labels prior to their purchases. (Dkt. 102 at 7.) However, the Court dismissed Plaintiffs' claims on the ground they were preempted. Specifically, with respect to the "front-of-label" claims, the Court found:

> In 2022, the FDA released guidance explaining that either the total protein (using the nitrogen method) or the digestible protein (using the PDCAAS method) is appropriate for nutrient content claims. . . .
>
> In this case, Plaintiffs have misinterpreted [FDA] regulations and attempt to incorrectly claim that they required Defendant to use the more exacting PDCAAS methodology for such *front-of-the-label* protein claims. . . . Plaintiffs rely entirely on cases decided before issuance of the FDA guidance. . . . Virtually all of those same courts have since declined to follow those decisions since the FDA guidance in question was issued. See, e.g., Nacarino v. Kashi Co., 584 F. Supp. 3d 806, 811, 811 n.4 (N.D. Cal. 2022) ("The plaintiffs also point out that district courts addressing this issue [protein values] have come out the other way. Fair enough. But for the reasons discussed above, this Court sees the issue differently and declines to follow their lead. . . . It is also worth noting that these [protein value] rulings came down before the FDA issued its most recent guidance on the topic."); Chong v. Kind LLC, 585 F. Supp. 3d 1215 (N.D. Cal. 2022) (holding that Minor was incorrectly decided and following the reasoning in Nacarino).

> The suggestion that Defendant should have used the corrected protein calculation is beyond what is required by the FDCA, and thus is expressly preempted.

(Dismissal Order at 12-13 (internal quotation marks omitted).) With respect to the %DV omission claims, the Court found these claims were impliedly preempted because they were "inextricably intertwined with the FDCA regulations, in the sense that they heavily rely on FDCA violations to establish that the statements at issue are misleading," and because Plaintiffs failed to make "an independent argument under the state consumer laws" that it was misleading to omit the %DV. (*Id.* at 15-16.) The Court granted Plaintiffs' leave to amend, but advised that any amended pleading must fit "within the 'narrow gap' between implied and express preemption." (*Id.* at 16.)

E. The SAC

On November 14, 2023, Plaintiffs filed the SAC. The SAC does not plead any additional facts. As shown in the redline attached as Exhibit A, the SAC does include seven additional paragraphs arguing that "Plaintiffs are not suing for some technical violation of federal food labeling regulations" and that federal law requires inclusion of %DV on some products because "the quality of the protein . . . would affect a reasonable consumer's purchasing decision . . . ." (SAC ¶¶ 36, 45-51.) The SAC does not allege that the Plaintiffs' share their lawyers' view about the importance of %DV.

ARGUMENT

Federal Rule of Civil Procedure 12(c) permits any party to move for judgment on the pleadings "[a]fter the pleadings are closed—but early enough not to delay trial." Fed.R.Civ.P. 12(c).

When such a motion is based on failure to state a claim, the standard for granting it is "identical" to the standard for a motion under Federal Rule of Civil Procedure 12(b)(6), *Patel v. Contemp. Classics of Beverly Hills*, 259 F.3d 123, 126 (2d Cir. 2001), which requires the plaintiff

to "assert a cognizable claim and allege facts that, if true, would support such a claim." *Boddie v. Schnieder*, 105 F.3d 857, 860 (2d Cir. 1997). A motion for judgment on the pleadings may also challenge subject matter jurisdiction. *U.S. ex rel. Phipps v. Comprehensive Cmty. Dev. Corp.*, 152 F. Supp. 2d 443, 448 (S.D.N.Y. 2001); *United States v. New Silver Palace Rest., Inc.*, 810 F. Supp. 440, 441–42 (E.D.N.Y. 1992). The question of a court's subject matter jurisdiction is not waivable and may be raised at any point in a case. *Lyndonville Sav. Bank & Tr. Co. v. Lussier*, 211 F.3d 697, 700 (2d Cir. 2000). Rule 12(c) motions based on subject matter jurisdiction are governed by the same standard as motions under Rule 12(b)(1). *Phipps*, 152 F. Supp. 2d at 449; *New Silver Palace*, 810 F. Supp. at 441. Rule 12(b)(1) motions may properly include evidence outside the pleadings, *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000), and plaintiffs bear "the ultimate burden of proving the Court's jurisdiction by a preponderance of the evidence." *Phipps*, 152 F. Supp. at 449. As a result, the standard used to evaluate such motions is "similar to that for summary judgment under Fed.R.Civ.P. 56." *Id.*[2]

I. PLAINTIFFS' FRONT-OF-LABEL CLAIMS ARE PREEMPTED FOR THE SAME REASONS THE COURT FOUND IN THEDISMISSAL ORDER

The FDCA expressly preempts all state causes of action that are "not identical to" federal requirements. 21 U.S.C. § 343-1(a)(5). As a result, any state law that seeks to prohibit labeling that federal law permits is preempted. *See Colella v. Atkins Nutritionals, Inc.*, 348 F. Supp. 3d 120, 134–35 (E.D.N.Y. 2018).

As the Court explained in the Dismissal Order, in 2022 the FDA issued "guidance explaining that either the total protein (using the nitrogen method) or the digestible protein (using

[2] A Rule 12(c) motion for judgment on the pleadings need not be treated as a motion for summary judgment for a court to consider materials outside the pleadings because the Rule 12(b)(1) standard already permits consideration of such materials. *Phipps*, 152 F. Supp. at 449, n.2 (noting that there was "no need for discovery" from moving defendants because all information relevant to subject matter jurisdiction was within plaintiff's knowledge and control).

the PDCAAS method) is appropriate for nutrient content claims." (Dismissal Order at 12.) Since then, courts have uniformly held that the FDCA expressly preempts a claim under state law that a protein content claim is misleading when the total protein is calculated using the nitrogen method. (*Id.* (collecting cases)); *see also Brown v. The J.M. Smucker Co.*, No. 21-CV-06467-HSG, 2022 WL 3348603, at *4 (N.D. Cal. Aug. 12, 2022); *Hinkley v. Baker Mills, Inc.*, No. 2:21-CV-00221-BSJ, 2022 WL 1767108, at *2 (D. Utah Apr. 26, 2022); *Brown v. Natures Path Foods, Inc.*, No. 21-CV-05132-HSG, 2022 WL 717816, at *7 (N.D. Cal. Mar. 10, 2022).

The SAC pleads no additional facts in support of its front-of-label claims, nor offers any other reason the Court should disturb its prior ruling. (*See* Kwasniewski Decl. Ex. A (Redline of SAC).) Accordingly, the Court should dismiss the claims again.

II. PLAINTIFFS' %DV OMISSION CLAIMS ARE PREEMPTED FOR THE SAME REASONS THE COURT FOUND THE DISMISSAL ORDER

As the Court explained in the Dismissal Order, "Express and implied preemption under the FDCA 'operate in tandem' and 'have created what some federal courts have described as a 'narrow gap' for pleadings." (Dismissal Order at 14 (quoting *Glover v. Bausch & Lomb*, 6 F.4th 229, 237 (2d Cir. 2021) ("The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted . . .) but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted . . . .)."). Whether Plaintiffs' claims can fit through this narrow gap turns on "whether these FDCA regulations constitute a 'critical element' of their case." (Dismissal Order at 14 (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001)).)

In the Dismissal Order, the Court found that Plaintiffs' %DV omission claims were impliedly preempted because Plaintiffs "rely on the FDCA regulations to claim that the failure to include a %DV resulted in a misrepresentation." (Dismissal Order at 15.) The SAC similarly

relies on the FDCA regulations. Like the FAC, the SAC "includes an entire portion . . . dedicated to laying out the FDCA regulations" (*Id.*), although Plaintiffs have shortened some of the lengthier paragraphs reciting federal law. (SAC ¶¶ 25-35.) Like the FAC, the SAC contains the same formulaic allegations that each Plaintiff would not have purchased the product had Ancient Nutrition "disclosed the amount of %DV as required by law . . . ." (SAC ¶¶ 54, 57; *see also* Dismissal Order at 15-16.)

The SAC alleges no additional facts showing that Plaintiffs, separate and apart from the federal regulations, cared about the %DV or its absence on the products. Nor could it, consistent with Plaintiffs' deposition testimony that they did not understand what %DV was or that it had no effect on their purchasing decisions. (Dunn Dep. Tr. at 47:7-10; 49:3-5; 50:10-51:7; 52:15-18; 53:20-54:4; Diaz Dep. Tr. at 57:18-58:6.)

The only additional allegations in the SAC are seven paragraphs asserting that some consumers (but not the Plaintiffs) care about %DV because they care about the "quality of the protein" contained in Ancient Nutrition's products. (SAC ¶ 45.) Even if these allegations were true, and not merely legal conclusions added to avoid dismissal, they fail to show the SAC's claims are not impliedly preempted. %DV is a creation of federal, not state, law. If, as Plaintiffs allege, consumers care about %DV as a measure of protein quality, that could only be true if consumers understand the complex web of federal regulations regarding the calculation of protein content and PDCAAS. Absent such an understanding, the omission of %DV would be meaningless, especially since the total protein content is properly disclosed. Thus, under Plaintiffs' new theory, the alleged FDCA violation remains a "critical element" of their case.

Alternatively, the SAC alleges that Ancient Nutrition has a duty under both federal and "parallel state law" to disclose a %DV. (SAC ¶ 47.) Plaintiffs allege this duty arises under state law because Ancient Nutrition "obfuscate[s]" the type of protein in its bone broth products. (*Id.* at

¶ 48.) This is not correct—the labels contain a detailed breakdown of how much collagen, chondroitin, hyaluronic acid, and glucosamine are contained in each serving. (RJN Ex. 3.) The labels repeatedly tout the benefits of collagen, which is what Plaintiffs testified they actually wanted. (Diaz Dep. Tr. at 57:18-58:6.) And again, %DV is a creation of federal law, meaning that the alleged federal violation would necessarily be an element of any state law claim to enforce this supposed duty. Thus, the SAC fails to fit through the "narrow gap" between express and implied preemption.

III. PLAINTIFFS FAIL TO ALLEGE RELIANCE, CAUSATION, OR INJURY ARISING FROM THEIR NEW %DV OMISSION THEORY

Even if Plaintiffs' new %DV omission theory is not preempted, it separately fails because Plaintiffs do not plausibly state a claim for relief. Each of Plaintiffs' claims require Plaintiffs to plead they relied on the alleged omission, that it caused their injury, and that they suffered an injury cognizable at law. *City of New York v. Smokes-Spirits.Com, Inc*., 12 N.Y.3d 616, 623 (2009) (actual injury requirement applies to claims under New York General Business Laws §§ 349 and 350); *In re Tobacco II Cases*, 46 Cal. 4th 298, 326 (2009) (UCL requires reliance, causation, and injury); *Caro v. Proctor & Gamble Co.*, 18 Cal. App. 4th 644, 688 (1993) (CLRA requires reliance, causation, and injury). Similar allegations are required for Plaintiffs to prevail on their fraudulent concealment cause of action. *Cnty. of Santa Clara v. Atl. Richfield Co.*, 137 Cal. App. 4th 292, 329 (2006); *Swersky v. Dreyer & Traub*, 643 N.Y.S.2d 33, 36 (App. Div. 1996).[3]

[3] As to the remaining common law causes of action in the SAC, it appears that Plaintiffs' express warranty cause of action is directed only at the front-of-product statement of protein content, and is thus preempted as discussed in Section I. If it is not, then the claim also fails for lack of causation and thus injury. *Goldemberg v. Johnson & Johnson Consumer Companies, Inc*., 8 F. Supp. 3d 467, 482 (S.D.N.Y. 2014); *Williams v. Beechnut Nutrition Corp*., 185 Cal.App.3d 135, 142 (1986). Plaintiffs' unjust enrichment cause of action is duplicative of their other claims and

Under Plaintiff's new theory, Plaintiffs allege the labels were misleading not merely because they violate the FDCA, but because the omission of %DV means the Plaintiffs could not determine the "quality" of the protein in the products. To suffer an injury under this theory, Plaintiffs must plead they saw that the products did not include a %DV and, based on their familiarity with the federal regulations regarding protein content claims and PDCAAS, inferred that the products contained protein of a higher "quality" than the collagen, chondroitin, hyaluronic acid, and glucosamine disclosed on the labels. The SAC contains no such allegations. Indeed, it assiduously avoids saying that the actual Plaintiffs, as opposed to hypothetical consumers, share in their lawyers' theory about the meaning and materiality of %DV.

For these very reasons, courts evaluating similar theories have held that omission of %DV, without specific factual allegations that plaintiffs relied on that omission, is not sufficient to state a claim. *Swartz v. Dave's Killer Bread, Inc.*, 2022 WL 1766463, at *6 (N.D. Cal. May 20, 2022); *Brown v. Natures Path Foods, Inc.*, No. 21-CV-05132-HSG, 2022 WL 717816, at *4 (N.D. Cal. Mar. 10, 2022) ("What is missing are facts allowing the Court to reasonably infer that Plaintiffs made their purchasing decisions based on anything other than the Products' front labels."); *see also Chong*, 2022 WL 464149, at *4 n.1 (N.D. Cal. Feb. 15, 2022) (("Dismissal [of claims based on omission of %DV] likely would also be warranted on grounds that plaintiffs have not alleged a cognizable injury arising from the omissions."). This Court should follow these decisions and find Plaintiffs fail to plausibly allege reliance, causation, or injury, which is fatal to their claims.

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thus fails with them, and is also subject to dismissal as duplicative. *Zottola v. Eisai Inc.,* 564 F. Supp. 3d 302, 318 (S.D.N.Y. 2021) (applying New York law to dismiss unjust enrichment claim); *Brazil v. Dole Food Co*., 935 F. Supp. 2d 947, 967 (N.D. Cal. 2013) (same under California law).

IV. PLAINTIFFS LACK STANDING TO PURSUE THEIR %DV OMISSION CLAIMS

Plaintiffs' new %DV omission theory separately fails because Plaintiffs lack Article III standing. To establish Article III standing, a plaintiff must plead (1) that he "suffered an injury-in-fact—an invasion of a legally protected interest which is (a) concrete and particularized ... and (b) actual or imminent, not conjectural or hypothetical"; (2) that there was a "causal connection between the injury and the conduct complained of"; and (3) that it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). In other words, "'Article III grants federal courts the power to redress harms that defendants cause plaintiffs, not a freewheeling power to hold defendants accountable for legal infractions.'" *TransUnion LLC v. Ramirez*, 594 U.S. 413, 427 (2021) (quoting *Casillas v. Madison Avenue Assocs., Inc*., 926 F.3d 329, 332 (7th Cir. 2019). "Only those plaintiffs who have been *concretely* harmed by a defendant's statutory violation may sue that private defendant over that violation in federal court." *TransUnion*, 594 U.S. at 427 (emphasis in original). And "plaintiffs must demonstrate standing for each claim that they press and for each form of relief that they seek . . . ." *Id.* at 431.

In its prior ruling, the Court found that the Plaintiffs had standing because they alleged they saw the front and back of the labels and relied on them in making their purchasing decision. (Dismissal Order at 7.) But this conclusion was based on Plaintiffs' old theory, under which a violation of the FDCA was also a violation of state consumer protection laws. Plaintiffs' new theory requires Plaintiffs to prove they did not just see the labels but inferred from the absence of %DV and their understanding of federal protein content regulations that the product contained a higher "quality" of protein than it supposedly in fact did.

Plaintiffs lack standing to proceed under such a theory because both Plaintiffs testified they did not specifically recall reading the NFP before making their purchases. (Dunn Dep. Tr. at

26:6-10; 28:24-29:4); (Diaz Dep. Tr. at 30:16-21 (indicating that she "normally just glimpse(s) at" product labels)). Both plaintiffs also gave testimony that they did ***not*** rely on the missing %DV. When asked about the basis for their claims against Ancient Nutrition, both plaintiffs testified that their only reason for suing was the alleged inaccuracy of the 20 grams of protein statement—neither indicated that the suit was at all motivated by the absence of a %DV. (Dunn Dep. Tr, at 47:7-10; 49:3-5; Diaz Dep. Tr. at 8:20-9:5.) Plaintiff Dunn testified that he did not "know offhand what [%DV] means," and that "[t]he percentage [DV] does not make a difference to me. It was the amount, it was the 20 grams that mattered to me." (Dunn Dep. Tr. at 52:15-18; 53:20-54:4.) Plaintiff Diaz testified she only cared that the product contained collagen and hyaluronic acid, and its overall protein content was irrelevant to her purchasing decision. (Diaz Dep. Tr. at 57:15-58:5.) She also testified that she is currently purchasing collagen products from other manufacturers—over a year after becoming involved in this lawsuit—but cannot say what %DV protein any of those products provide. (Diaz Dep. Tr. at 22:6-23:14.)

In light of this testimony, there is no plausible set of facts Plaintiffs could allege to show they have standing to pursue their new %DV omission theory.

V. LEAVE TO AMEND SHOULD BE DENIED

"[L]eave to amend a complaint may be denied when amendment would be futile." *Nielsen v. Rabin*, 746 F.3d 58, 62 (2d Cir. 2014). Here, it is apparent that further amendment would be futile. Plaintiffs have already amended the Complaint twice. Most recently, the Court gave Plaintiffs sixty days to file the SAC and clearly delineated the "narrow gap" through which the claims must fit to not be preempted. Plaintiffs did not comply with the Court's Dismissal Order, and instead simply added a few paragraphs of attorney argument. (Kwasniewski Decl. Ex. A.). This case has been pending for over two years. Plaintiffs should not be permitted to further consume scarce judicial resources litigating their futile claims.

CONCLUSION

For the foregoing reasons, the Court should dismiss Plaintiffs' claims with prejudice.

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Respectfully Submitted,

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